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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,173	08/23/2001	Henry M. Israel	1093NES-US	1648

7590 11/09/2004

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EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,173

Applicant(s)

ISRACL, HENRY M.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 14, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 14, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4, lines 14 and 15 "tapers" is confusing and inaccurate since a taper, by definition, is a reduction of the thickness or width of an object, i.e. a convergence. Thus, this term is inconsistent with the term "divergent" in claim 4, line 13.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The embolic material defined in claim 1 is part of the human body and is thus non-statutory subject matter.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Claren et al. (6,524,333). Claren et al. disclose a stent assembly comprising an upstream portion (e.g. one end portion of the stent 11) that is inherently adapted to

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modify a flow characteristic of embolic material disposed in a blood stream flowing through said upstream portion (The flow characteristic of blood as well as any embolic material flowing in a blood vessel is modified when it enters the stent since the stent reduces the cross-section of the flow path as compared with the blood vessel.) and a downstream portion (e.g. the other end portion of the stent 11) comprising a trapping region with embolic material stored therein. (Stenotic material is inherently trapped between the stent and the blood vessel wall and extends into the openings in the mesh of the stent as indicated on page 1, lines 16-19 of applicant's specification. This stenotic material is embolic material.) Note that Claren et al. disclose an embodiment without cover 12 (col. 3, lines 26-31). In this embodiment, the stent mesh has openings which can receive stenotic material since the stent is not covered by cover 12. Alternatively, the endotel cells which cover the stent as described in col. 3, lines 25-26 of Claren et al. is embolic material trapped and stored in the stent. As to claim 3, Claren et al. disclose an upstream portion (one of the stents 11 described in col. 3, lines 31-35) and a downstream portion (another one of the stents 11 described in col. 3, lines 31-35) that is separate and discontinuous from the upstream portion.

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Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yachia et al. (5,246,445) in view of Claren et al. (6,524,333). Yachia et al., in figure 1b, disclose a downstream portion (the entire stent) comprising a trapping region for trapping embolic material. (This portion is inherently capable of trapping embolic material since, like the trapping region 22 of applicant's invention, it diverges at the bulges 2 along the flow path of the stent to allow the embolic material to remain in the divergent regions or bulges of the stent.) Yachia et al. fail to disclose an upstream portion separate and discontinuous from the downstream portion. However, it is old and well known to deploy a plurality of stents in a blood vessel in order to obtain the advantage of enlarging the lumen of the blood vessel at multiple locations of obstructions. For example, Claren et al. teach that a plurality of stents should be deployed in a blood vessel in order to effectively treat the blood vessel along a length thereof (col. 3, lines 31-35). It would have been obvious to deploy two of the Yachia et al. stents in a blood vessel so that it too would have this advantage. The second stent would be the claimed upstream portion. As to claim 23, Yachia et al. fail to disclose a restrictor element. However, it is well known in this art to provide restrictor elements to stents so that the

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expansion of the stent is precisely and automatically limited. It would have been obvious to include a restrictor element in the Yachia et al. stent so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03).

Claims 4 and 14 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Applicant's arguments with respect to claims 1-3, 22 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

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expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703)308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
11/4/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731